

Notice of Allowability	Application No.	Applicant(s)	
	09/830,221	HAYNES ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/3/04.
2. ☒ The allowed claim(s) is/are 28-43.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

The first line of the specification has been amended to include the continuing data:

This application is a U.S. national stage application of PCT International Application No. PCT/US99/24769 and claims priority to provisional application 60/122,446, filed March 2, 1999, now abandoned, and provisional application 60/105,469 filed October 23, 1998, now abandoned.

At the interview on February 17, 2003, the following prior art was discussed of interest.

Audonnet et al. (WO 98/03660) claim a vaccine formulation for felines comprising a plasmid expressing heterologous genes, one of which is glycoprotein G from rabies, see claim 1. However, Audonnet et al. do not complex the polynucleotide vaccine formulation with a cationic lipid. Further, Audonnet et al. do not provide a working example demonstrating prophylactic efficacy in felines. The data in the working examples of the instant specification clearly shows unexpected results with the claimed formulation because cats exhibited a protective, neutralizing antibody response and mice did not. Therefore, it is evident that the asserted protective efficacy of the vaccine composition of Audonnet et al. is indeterminable because the reference does not evaluate the immune response upon administrations to cats.

Cuisinier et al. (Vaccine. July, 1997; 15 (10): 1085-1094) teach DNA vaccination with plasmids encoding structural FIV structural proteins. However, the data obtained by Cuisinier et

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al. do not provide any evidence of success of administering a plasmid encoding rabies glycoprotein G, especially since Cuisinier et al. teach that cats did not develop neutralizing titers to FIV gp120, see the results and discussion sections. Further, Cuisinier et al. do not complex the plasmid with a cationic lipid.

Yokoyama et al. (FEMS. 1996; 14: 221-230) teach that DNA complexed with cationic lipids induces antibodies and CTL. However, Yokoyama et al. do not teach or suggest the effect of administering such a composition expressing rabies glycoprotein G to cats. As discussed above, the data in the working examples demonstrate unexpected neutralizing antibody titers in cats where none was observed in mice. Yokoyama et al. do not indicate that there would be a difference in immune response to a DNA complex with a cationic lipid in different hosts.

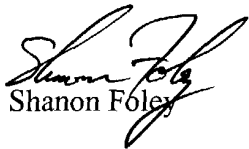
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

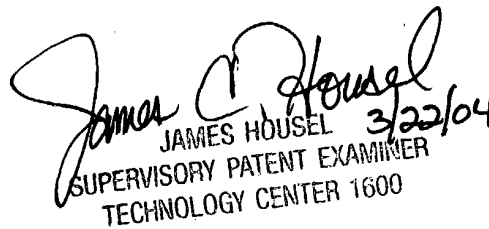
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley


JAMES HOUSEL 3/22/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600